

REMARKS

Claim Status

Claims 2, 11, 17-19 and 21 are cancelled.

Claims 22-27 are new and have written support in the original application (e.g., page 2, lines 8-20; page 7, lines 27-30).

Applicants respectfully submit that the foregoing amendments to the claims do not introduce any new subject matter to the application. With the present amendments, there are twenty-one claims pending, namely claims 1, 3-10, 12-16, 20 and 22-27.

Claim Rejections – 35 USC § 112, First Paragraph (Written Description)

Claims 1-16 and 18-21 stand rejected under 35 USC § 112, first paragraph, as lacking written description by the specification. In lodging this rejection, the Examiner alleges that there “is no description in the specification disclosing ‘applying a stabilizer to said support and incubating said stabilizer on said support for about 12-14 hours [at] about 4 degrees C.’” This phrase, which was added to claim 1 in the April 14, 2010 Response, is alleged by the Examiner to constitute new matter. Applicants respectfully traverse this rejection for the following reasons.

WIPO publication No. WO 2005/062050 was filed in the instant application on June 21, 2006 as part of the original application. Claim 1 of WO 2005/062050 recites “adding a stabilizer solution to the wells of the solid support...[and] incubating for a period ranging between 12 and 14 hours at about 4°C.” Furthermore, this language is embodied in relevant steps performed in Examples 1-3 of the original specification (e.g., page 9, line 23; page 11, line 23; page 13, line 22). In view of these remarks, Applicants respectfully submit that this rejection should be withdrawn.

Claim Rejections – 35 USC § 103(a)

Five different rejections under 35 U.S.C. § 103(a) are leveled in the Office Action.

Claims 1, 2, 4, 5, 7-11, 16, 19 and 20

In the first rejection, claims 1, 2, 4, 5, 7-11, 16, 19 and 20 are alleged to be obvious over Rech-Weichselbraun et al. (US Appl. Publ. 2004/0171087) in view of Mitoma et al. (Patent Abstracts of Japan, 63111467, 1988), and Gatto-Menking et al. (US Appl. Publ. 2003/0108973). The Examiner further refers to Sawyer et al. (US Patent No. 5,602,041; c. 1, ll. 13-42), which discloses the stabilizing function of blocking agents. Applicants respectfully traverse this rejection for the following reasons.

The invention is drawn, for example, to a method for preparing a ready-to-use solid support for performing an ELISA. This method comprises a series of steps involving freeze-drying and the addition of stabilizers in a certain manner allowing the immobilization or impregnation of antibodies on a solid support. As disclosed in the instant specification (page 2, lines 7-20), the ready-to-use solid support prepared following the claimed method has unexpected advantages over the prior art, in particular Rech-Weichselbraun. For example, the claimed support enables a user to perform ELISA in a single step within the short period of time of **150 minutes**, which is remarkably shorter than the 250 minutes required in the prior art. Also, **no additional reagents** such as biotin and streptavidin are necessary to enhance the sensitivity of assays performed using the claimed support.

Furthermore, the multiple proteins impregnated on the claimed support are stable and can be used at any time for ELISA. This **stability of multiple proteins** circumvents the problem of having to obtain conjugated or unconjugated antibodies from various sources, thereby reducing

assay time and complexity. This feature is advantageous since the stability of immobilized proteins is a critical factor for successful detection and estimation of target protein levels in ELISA. The claimed support therefore reduces the number of steps that an end-user must perform in an ELISA. As another benefit, the end-user does not have to rely on items typically required to enhance ELISA sensitivity, thereby reducing time and cost.

None of the prior art cited in the pending Office Action teaches the immobilization and stabilization of multiple proteins on a solid support, and performing ELISA using such a support in the short period of time of 150 minutes. Therefore, the subject matter of the pending claims cannot be considered to result from mere optimization of general conditions. The cited prior art thus does not render the claimed invention as being obvious.

Applicants respectfully submit that this particular obviousness rejection should be withdrawn.

Claims 3, 12 and 13

In the second rejection, claims 3, 12 and 13 are alleged to be obvious over Rech-Weichselbraun, Mitoma, and Gatto-Menking as applied in the first rejection in further view of Rogan et al. (1999, *Food Control* 10:407-414). Rogan is cited as teaching 5-enolpyruvylshikimate-3-phosphate synthase as the protein to be detected by ELISA.

As discussed in the above remarks, Rech-Weichselbraun, Mitoma, and Gatto-Menking do not render the pending claims as being obvious. Rogan does not cure this deficiency. Therefore, Applicants respectfully submit that this particular obviousness rejection should be withdrawn.

Claim 6

In the third rejection, claim 6 is alleged to be obvious over Rech-Weichselbraun, Mitoma, and Gatto-Menking as applied in the first rejection in further view of Vogt et al. (1987, *J.*

Immunol. Meth. 101:43-50). Vogt is cited as teaching fish gelatin as a blocking/stabilizing agent.

As discussed in the above remarks, Rech-Weichselbraun, Mitoma, and Gatto-Menking do not render the pending claims as being obvious. Vogt does not cure this deficiency. Therefore, Applicants respectfully submit that this particular obviousness rejection should be withdrawn.

Claims 14, 15 and 18

In the fourth rejection, claims 14, 15 and 18 are alleged to be obvious over Rech-Weichselbraun, Mitoma, Gatto-Menking and Rogan as applied against claims 1-5, 7-13, 16, 19 and 20 (first and second rejections) in further view of Padgette et al. (1995, *Crop Sci.* 35:1451-1461). Padgette is cited as teaching that alkaline phosphatase and antibodies obtained from the class Mammalia can be used in ELISA.

As discussed in the above remarks, Rech-Weichselbraun, Mitoma, Gatto-Menking and Rogan do not render the pending claims as being obvious. Padgette does not cure this deficiency. Therefore, Applicants respectfully submit that this particular obviousness rejection should be withdrawn.

Claim 21

In the fifth rejection, claim 21 is alleged to be obvious over Rech-Weichselbraun, Mitoma, and Gatto-Menking as applied in the first rejection in further view of Adang et al. (US Appl. Publ. 2004/0254364).

Claim 21 is cancelled in the above amendment. Therefore, Applicants respectfully submit that this rejection is moot.

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Aside from the fees for a Request for continued Examination (RCE) and additional claims, no other fee is believed to be due in connection with this response. However, the Commissioner is hereby authorized to charge any underpayment of fees to Howrey LLP Deposit Account No. 08-3038/04725.0002.PCUS00.

Respectfully submitted,

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